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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,668	03/12/2001	E. George Wolf JR.		1995

7590 07/31/2002
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San Antonio, TX 78248

EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/31/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

09/804,668

WOLF, E. GEORGE

Examiner

Art Unit

David A Redding

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 2 and 3 in Paper No. 4 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: between elements (a)-(l).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2-14 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,837,390 (Reneau).

The Reneau patent discloses a **hyperbaric** organ preservation apparatus for preserving living organs. See the description of figure 1.

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6. Claims 2,4,5,6, are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,356,771 (O'Dell).

The O'Dell patent discloses a combined perfusion and oxygenation organ preservation apparatus comprising means for providing hyperbaric oxygenation and temperature control. See description of figures 1-3a and column 2, lines 14- col.3.

7. Applicant is informed that amendments (changes) to the application must be executed in accordance with 37 C.F.R. 1.121. A copy of this rule is included in this action.

8. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 703-308-3910. The examiner can normally be reached on M,T,Th,Fr, 7:30-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David A Redding
Primary Examiner
Art Unit 1744

D.A.R.
July 29, 2002

clarification for appeal may be accomplished with only nominal further consideration. Interviews merely to restate arguments of record or to discuss new limitations which would require more than nominal reconsideration or new search should be denied. See MPEP § 714.13.

Interviews may be held after the expiration of the shortened statutory period and prior to the maximum permitted statutory period of 6 months without an extension of time. See MPEP § 706.07(f).

A second or further interview after a final rejection may be held if the examiner is convinced that it will expedite the issues for appeal or disposal of the application.

713.10 Interview Preceding Filing Amendment Under 37 CFR 1.312

After an application is sent to issue, it is technically no longer under the jurisdiction of the primary examiner. 37 CFR 1.312. An interview with an examiner that would involve a detailed consideration of claims sought to be entered and perhaps entailing a discussion of the prior art for determining whether or not the claims are allowable should not be given. Obviously an applicant is not entitled to a greater degree of consideration in an amendment presented informally than is given an applicant in the consideration of an amendment when formally presented, particularly since consideration of an amendment filed under 37 CFR 1.312 cannot be demanded as a matter of right.

Requests for interviews on cases where a notice of allowance has been mailed should be granted only with specific approval of the Technology Center Director upon a showing in writing of extraordinary circumstances.

714 Amendments, Applicant's Action

37 CFR 1.121. Manner of making amendments in application.

(a) *Amendments in applications, other than reissue applications.* Amendments in applications, other than reissue applications, are made by filing a paper, in compliance with § 1.52, directing that specified amendments be made.

(b) *Specification other than the claims and listings provided for elsewhere (§ § 1.96 and 1.825).* —

(1) *Amendment by instruction to delete, replace, or add a paragraph.* Amendments to the specification, other than the claims and listings provided for elsewhere (§ § 1.96 and 1.825), may be made by submitting:

(i) An instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a deleted paragraph with one or more replacement paragraphs, or add one or more paragraphs;

(ii) Any replacement or added paragraph(s) in clean form, that is, without markings to indicate the changes that have been made; and

(iii) Another version of any replacement paragraph(s), on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of the paragraph(s). The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added paragraph or a deleted paragraph as it is sufficient to state that a particular paragraph has been added, or deleted.

(2) *Amendment by replacement section.* If the sections of the specification contain section headings as provided in § § 1.77(b), 1.154(b), or § 1.163(c), amendments to the specification, other than the claims, may be made by submitting:

(i) A reference to the section heading along with an instruction to delete that section of the specification and to replace such deleted section with a replacement section;

(ii) A replacement section in clean form, that is, without markings to indicate the changes that have been made; and

(iii) Another version of the replacement section, on one or more pages separate from the amendment, marked up to show all changes relative to the previous version of the section. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system.

(3) *Amendment by substitute specification.* The specification, other than the claims, may also be amended by submitting:

(i) An instruction to replace the specification;

(ii) A substitute specification in compliance with § 1.125(b); and

(iii) Another version of the substitute specification, separate from the substitute

specification, marked up to show all changes relative to the previous version of the specification. The changes may be shown by brackets (for deleted matter), or underlining (for added matter), or by any equivalent marking system.

(4) *Reinstatement* : Deleted matter may be reinstated only by a subsequent amendment presenting the previously deleted matter.

(c) *Claims.* —

(1) *Amendment by rewriting, directions to cancel or add* . Amendments to a claim must be made by rewriting such claim with all changes (e.g., additions, deletions, modifications) included. The rewriting of a claim (with the same number) will be construed as directing the cancellation of the previous version of that claim. A claim may also be canceled by an instruction.

(i) A rewritten or newly added claim must be in clean form, that is, without markings to indicate the changes that have been made. A parenthetical expression should follow the claim number indicating the status of the claim as amended or newly added (e.g., “amended,” “twice amended,” or “new”).

(ii) If a claim is amended by rewriting such claim with the same number, the amendment must be accompanied by another version of the rewritten claim, on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of that claim. A parenthetical expression should follow the claim number indicating the status of the claim, e.g., “amended,” “twice amended,” etc. The parenthetical expression “amended,” “twice amended,” etc. should be the same for both the clean version of the claim under paragraph (c)(1)(i) of this section and the marked up version under this paragraph. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added claim or a canceled claim as it is sufficient to state that a particular claim has been added, or canceled.

(2) A claim canceled by amendment (deleted in its entirety) may be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

(3) A clean version of the entire set of pending claims may be submitted in a single amendment paper. Such a submission shall be construed as directing the cancellation of all previous versions of any pending claims. A marked up version is required only for claims being changed by the current amendment (see paragraph (c)(1)(ii) of this section). Any claim not accompanied by a marked up version will constitute an assertion that it has not been changed relative to the immediate prior version.

(d) *Drawings* . Application drawings are amended in the following manner: Any change to the application drawings must be submitted on a separate paper showing the proposed changes in red for approval by the examiner. Upon approval by the examiner, new drawings in compliance with § 1.84 including the changes must be filed.

(e) *Disclosure consistency* . The disclosure must be amended, when required by the Office, to correct inaccuracies of description and definition, and to secure substantial correspondence between the claims, the remainder of the specification, and the drawings.

(f) *No new matter* . No amendment may introduce new matter into the disclosure of an application.

(g) *Exception for examiner’s amendments*: Changes to the specification, including the claims, of an application made by the Office in an examiner’s amendment may be made by specific instructions to insert or delete subject matter set forth in the examiner’s amendment by identifying the precise point in the specification or the claim(s) where the insertion or deletion is to be made. Compliance with paragraphs (b)(1), (b)(2) or (c)(1) of this section is not required.

(h) *Amendments in reissue applications*. Any amendment to the description and claims in reissue applications must be made in accordance with § 1.173.

(i) *Amendments in reexamination proceedings* : Any proposed amendment to the description and claims in patents involved in reexamination proceedings in both *ex parte* reexaminations filed under § 1.510 and *inter partes* reexaminations filed under § 1.913 must be made in accordance with § 1.530(d)-(j).

(j) *Amendments in provisional applications*: Amendments in provisional applications are not normally made. If an amendment is made to a provisional application, however, it must comply with the provisions of this section. Any amendments to a provisional application shall be placed in the provisional application file but may not be entered.

WHEN APPLICANT MAY AMEND

The applicant may amend:

(A) before or after the first examination and action and also after the second or subsequent examination or reconsideration as specified in 37 CFR 1.112;

(B) after final rejection, if the amendment meets the criteria of 37 CFR 1.116; and

(C) when and as specifically required by the examiner.

Amendments in provisional applications are normally made. If an amendment is made to a provisional application, however, it must comply with the provisions of 37 CFR 1.121. Any amendments to a provisional application will be placed in the provisional application file, but may not be entered.

MANNER OF MAKING AMENDMENTS

After March 1, 2001, all amendments to the specification, including the claims, must be made by replacement paragraph/section/claim in clean form (without underlining and bracketing) in order to eliminate (1) the need for the Office to enter changes to the text of application portions by handwriting in red ink, and (2) the presence of hard to scan brackets and underlining to improve the patent publishing process. This practice requires the applicant to provide a clean copy of an amended paragraph/section/claim together with a marked up version using applicant's choice of a marking system showing the changes being made which will aid the examiner. The marked up version must be based on the immediate previous version and indicate (by markings) how the previous version has been modified to produce the clean replacement paragraph(s), section(s), specification or claim(s) submitted in the current amendment. "Previous version" is defined as the version of record in the application as originally filed or from a previously entered amendment.

Amendments to the Specification

In order to delete, replace or add a paragraph to the specification of an application, the amendment must unambiguously identify the paragraph to be modified either by paragraph number (see MPEP § 608.01), page and line, or any other unambiguous method and be accompanied by the replacement paragraph(s) in clean form.

Where paragraph numbering has been included in an application as provided in 37 CFR 1.52(b)(6), applicants can easily refer to a specific paragraph by number when presenting an amendment. If a numbered paragraph is to be replaced by a single paragraph, the added replacement paragraph should be numbered with the same number of the paragraph being replaced. Where more than one paragraph is to replace a single original paragraph, the added paragraphs should be numbered using the number of the original paragraph for the first replacement paragraph, followed by increasing decimal numbers for the second and subsequent added paragraphs, e.g., original paragraph [0071] has been replaced with paragraphs [0071], [0071.1], and [0071.2]. If a numbered paragraph is deleted, the numbering of the subsequent paragraphs should remain unchanged.

37 CFR 1.121(b)(1)(ii) requires that the replacement or added paragraph(s) be in clean form. This means that the added or replacement paragraph(s) must not include any markings to indicate the changes that have been made. 37 CFR 1.121(b)(1)(iii) requires that a separate version of the replacement paragraph(s) accompany the amendment. The separate version must include each replacement paragraph with markings to show the changes relative to the previous version as an aid to the examiner. A marked up version, however, does not have to be supplied for any added paragraph(s) or any deleted paragraph(s), as it is sufficient to merely indicate or identify any paragraph that has been added or deleted.

Applicants are also permitted to amend the specification by replacement sections (e.g., as provided in 37 CFR 1.77(b), 1.154(b), or 1.163(c)). As with replacement paragraphs, the amended version of a replacement section is required to be provided in clean form, that is, without any markings to show the changes that have been made. A separate marked up version showing the changes in the section relative to the previous version must accompany the actual amendment as an aid to the examiner.

Applicants are also permitted to amend the specification by submitting a substitute specification, provided the requirements of 37 CFR 1.125(b) are met. An accompanying separate marked up version showing the changes in the specification relative to the previous version is also required.

Any subject matter deleted by amendment can only be reinstated by a subsequent amendment presenting the previously deleted subject matter. A direction by applicant to remove a previously entered amendment will not be permitted.

Amendments to the Claims

All amendments to a claim must be presented in the form of a rewritten claim. Any rewriting of a claim will be construed as a direction to cancel the previous version of the claim. See *In re Byers*, 230 F.2d 451, 455, 109 USPQ 53, 55 (CCPA 1956)(amendment of a claim by inclusion of an additional limitation had exactly the same effect as if the claim as originally presented had been canceled and replaced by a new claim including that limitation). Any rewritten or newly added claim must be submitted in clean form, that is, with no markings to indicate the changes that have been made, and must be accompanied by a marked up version separate from the amendment using applicant's choice of marking system to indicate the changes being made. A parenthetical expression should follow the claim number indicating the status of the claim as amended or newly added, e.g., "amended," "twice amended," or "new," in both the clean version and the marked up version. A marked up version does not have to be supplied for any added claims or any canceled claims. If a marked up version is supplied to show changes made to amended claims, however, applicant should identify (in the marked up version) any added or canceled claims with a statement, such as, "Claim 6 has been canceled." A canceled claim can be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

Applicants may submit a clean version (with no markings) of all of the pending claims in one amendment paper. Applicants may wish to consolidate all previous versions of pending claims from a series of separate amendment papers into a single clean version in a single amendment paper. Providing this consolidation of claims in the file will be beneficial to both the Office and the applicant for patent printing purposes. When rewriting a claim in the clean set, the parenthetical expression, if any, from the claim to be rewritten should not appear in the clean set. Thus, the only time a parenthetical expression should appear in the clean set is when a claim is being amended. See MPEP § 714.13 for submitting a clean set of claims under 37 CFR 1.116 and MPEP § 714.16 for submitting a clean set under 37 CFR 1.312. See also MPEP § 714.22(a).

It is recommended that the following format be used by applicants in complying with the revised amendment practice requirements. The amendment paper should include, in the following order:

- (A) a clean version of the amended (replacement) paragraph(s)/claim(s);
- (B) a remarks section (beginning on a separate sheet); and
- (C) a marked-up version (also beginning on a separate sheet) showing changes and clearly identified as **"Version with markings to show changes made."**

The submission of a clean version of all pending claims shall be construed as directing the cancellation of all previous versions of any pending claims. A marked up version would only be needed for claims being changed by the current amendment (see 37 CFR 1.121(c)(1)(ii)). Any claim not accompanied by a marked up version will constitute an assertion that it has not been modified relative to the immediate prior version. Thus, if applicant is not making any amendments to the claims, but is merely presenting all pending claims in clean form, without any underlining and bracketing, a marked up

version should not be submitted.

37 CFR 1.121(g) permits the Office to make amendments to the specification, including the claims, by examiner's amendments without paragraph/section/claim replacement in the interest of expediting prosecution and reducing cycle time. Additions or deletions of subject matter in the specification, including the claims, may be made by instructions to make the change at a precise location in the specification or the claims. See MPEP § 1302.04.